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Applicant: Shou, et al

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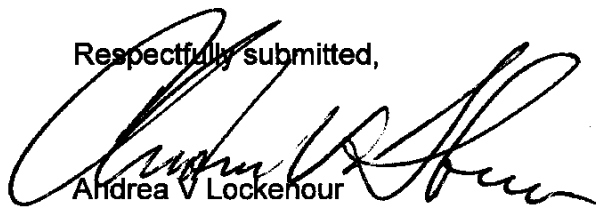
For: "METHODS FOR DETECTING Lp-PLA2 ACTIVITY AND INHIBITION OF Lp-PLA2 ACTIVITY"

Commissioner for Patents
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FILING OF AN INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. §1.97(b)

The attached list of citations on PTO Form 1449 is being submitted under the provisions of 37 CFR §1.56 and §1.97 for consideration by the United States Patent and Trademark Office, prior to the granting of this patent. Their inclusion herein should not, however, be construed as an admission that any particular cited document is effective prior art or that it discloses or renders obvious any aspect of the claimed invention. A copy of each cited document is enclosed, except U.S. Patent documents, and those references which are already part of the filewrapper. This statement is being filed within the time period specified in 37 CFR §1.97(b). No fee is required.

Respectfully submitted,



Andrea V. Lockenhour
Attorney for Applicants
Registration No. 51,962

GLAXOSMITHKLINE
Corporate Intellectual Property - UW2220
P.O. Box 1539
King of Prussia, PA 19406-0939
Phone (610) 270-7568
Facsimile (610) 270-5090

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| Form PTO-1449 | U.S. Department of Commerce Patent and Trademark Office | ATTY. DOCKET NO. PU60813 PCT/US | SERIAL NO. 10/599914 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use several sheets if necessary)</i> | | APPLICANT Shou, et al. | |
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U.S. PATENT DOCUMENTS

| Examiner Initial | | Document Number | Date | Name | Class | Subclass | Filing Date If Appropriate |
|------------------|----|-----------------|--------------|----------------|-------|----------|----------------------------|
| | AA | 2003/072747A1 | 17 Apr. 2003 | Cousens et al. | | | |
| | AB | 2002/102231A1 | 01 Aug. 2002 | Dietsch et al. | | | |
| | AC | US 6203790B1 | 20 Mar. 2001 | Cousens et al. | | | |
| | AD | US 5698403 | 16 Dec. 1997 | Cousens et al. | | | |
| | AE | 20050244913A1 | 03-Nov-2005 | Shou, et al. | | | |

FOREIGN PATENT DOCUMENTS

| | | Document Number | Date | Country | Class | Subclass | Translation | |
|--|----|-----------------|--------------|---------|-------|----------|-------------|----|
| | | | | | | | Yes | No |
| | BA | WO04089184A1 | 21 Oct 2004 | PCT | | | | |
| | BB | EP1318154A1 | 11 June 2003 | EPO | | | | |
| | BC | WO00/032808 | 08 June 2000 | PCT | | | | |
| | BD | JP 07059597 | 07 Mar. 1995 | Japan | | | | |
| | BE | EP816504A2 | 07 Jan. 1998 | EP | | | | |
| | BF | WO 9509921 A1 | 13 Apr. 1995 | PCT | | | | |
| | BG | JP 06116279A | 26 Apr. 1994 | Japan | | | | |
| | BH | WO05/001416A2 | 06 Jan 2005 | PCT | | | | |
| | BI | JP 2002-179545 | 20 June 2002 | Japan | | | | |

OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | | |
|--|----|---|
| | CA | Kosaka, T., et al., "Spectrophotometric Assay for Serum Platelet-Activating Factor Acetylhydrolase Activity," <i>Clinica Chimica Acta</i> (2000) 296(1-2):151-161. |
| | CB | Kosaka, T., et al., "Serum Platelet-Activating Factor Acetylhydrolase (PAFAH) Activity in more than 3000 Healthy Japanese," <i>Clinica Chimica Acta</i> (2001)312(1-2):179-183. |
| | CC | Koenig, W., et al., "Lipoprotein-Associated Phospholipase A ₂ Adds to Risk Prediction of Incident Coronary Events by C-Reactive Protein in Apparently Healthy Middle-Aged Men from the General Population" <i>Circulation</i> (Oct. 2004) 110(14):1903-1908. |
| | CD | Balafa, O., et al., "Urine of Patients with Nephritic Syndrome Contains the Plasma Type of PAF-Acetylhydrolase Associated with Lipoproteins," <i>Nephron Physiology</i> (2004)97(3):45-52. |
| | CE | Sarchielli, P., et al., "Platelet-Activating Factor (PAF) in Internal Jugular Venous Blood of Migraine without Aura Patients Assessed During Migraine Attacks," <i>Cephalagia</i> (2004) 24(8):623-630. |
| | CF | Karkabounas, A., et al., "Quantitative Fluorescence Determination of Phospholipase A ₂ and PAF Acetylhydrolase in Biological Fluids using High Performance Liquid Chromatography," <i>Chemistry and Physics of Lipids</i> (June 2004)130(1):69-70. |
| | CG | Brites, F., et al., "Paraoxonase I and Platelet-Activating Factor Acetylhydrolase Activities in Patients with Low HDL-Cholesterol Levels with or without Primary Hypertriglyceridemia," <i>Archives of Medical Research</i> (May 2004)35(3):235-240. |

| | |
|---|-----------------|
| EXAMINER | DATE CONSIDERED |
| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

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OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

| | |
|---|---|
| CH | Kujiraoka, T., et al., "Altered Distribution of Plasma PAF-AH between HDLs and other Lipoproteins in Hyperlipidemia and Diabetes Mellitus," <i>Journal of Lipid Research</i> (October 2003) 44:2006-14. |
| CI | Ito, T., et al., "Serum PAF-Acetylhydrolase (PAF-AH) in Hepatobiliary Disease," <i>Japanese Pharmacology and Therapeutics</i> (2002) 30/Suppl. 2. |
| CJ | Unno, N., et al., "Single Nucleotide Polymorphism (G ⁹⁹⁴ →T) in the Plasma Platelet-Activating Factor-Acetylhydrolase Gene is Associated with Graft Patency of Femoropopliteal Bypass," <i>Surgery</i> (2002) 132(1):66-71. |
| CK | Dada, N., et al., "Lp-PLA2: An Emerging Biomarker of Coronary Heart Disease," <i>Expert Review of Molecular Diagnostics</i> (Jan. 2002) 2(1):17-22. |
| CL | Ibe, B., et al., "Platelet Activating Factor Acetylhydrolase Activity in Lamb Lungs is Up-Regulated in the Immediate Newborn Period," <i>Molecular Genetics and Metabolism</i> (Jan. 2000) 69(1):46-55. |
| CM | Deigner, H., et al., "Novel reversible, irreversible and fluorescent inhibitors of platelet-activating factor acetylhydrolase as mechanistic probes," <i>Atherosclerosis</i> (May 1999) 144(1):79-90. |
| CN | Kitsioulis, E., et al., "Differential Determination of Phospholipase A(2) and PAF-Acetylhydrolase in Biological Fluids Using Fluorescent Substrates," <i>Journal of Lipid Research</i> (Dec. 1999) 40(12):2346-2356. |
| CO | Hendrickson, H.S., et al., "Intramolecularly Quenched BODIPY-Labeled Phospholipids Analogs in Phospholipase A ₂ and Platelet-Activating Factor Acetylhydrolase assays and <i>in vivo</i> Fluorescence Imaging," <i>Analytical Biochemistry</i> (Dec. 1999) 276(1):27-35. |
| CP | Akiyama, M., et al., "Identification of a Major PAF Acetylhydrolase in Human Serum/Plasma as a 43 KDa Glycoprotein Containing about 9 kDa Asparagine-Conjugated Sugar Chain(s)," <i>Journal of Biochemistry</i> (May 1998) 123(5):786-789. |
| CQ | Servillo, L., et al., "Simultaneous Determination of Lysophospholipids by High-performance Liquid Chromatography with Fluorescence Detection," <i>Journal of Chromatography</i> (1997) 689(2):281-286. |
| CR | Patrick, D.A., et al., "Reduced PAF-Acetylhydrolase Activity is Associated with Postinjury Multiple Organ Failure," <i>Shock</i> (Mar. 1997) 7(3):170-174. |
| CS | Tsukioka, K., et al., "Increased Plasma Level of Platelet-Activating Factor (PAF) and Decreased Serum PAF Acetylhydrolase (PAFAH) Activity in Adults with Bronchial Asthma," <i>Journal of Investigational Allergology and Clinical Immunology</i> (1996) 6(1):22-29. |
| CT | Balestrieri, C., et al., "Measurement of Platelet-Activating Factor Acetylhydrolase Activity by Quantitative High-Performance Liquid Chromatography Determination of Coumarin-Derivatized 1-0-alkyl-2-sn-lysoglycerol-3-phosphorylcholine," <i>Analytical Biochemistry</i> (Jan. 1996) 233(2):145-50. |
| EXAMINER | |
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| EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. | |

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| | |
|-----|--|
| CU | Riehl, T. E. and Stenson W.F., "Platelet-activating factor acetylhydrolases in Caco-2 cells and epithelium of normal and ulcerative colitis patients," <i>Gastroenterology</i> (1995)109(6):1826-1834. |
| CV | Masaki, A., et al., "New Serum PAF acetylhydrolase detection method used with the Blotting Method and Beta of H ³ acetyl-PAF," <i>Proceedings of Japanese Conference on the Biochemistry of Lipids</i> (1994)36:43-46. |
| CW | Hemmings, R., et al., "Platelet-Activating Factor Acetylhydrolase Activity in Peritoneal Fluids of Women with Endometriosis," <i>Obstetrics and Gynecology</i> (Feb. 1993)81(2):276-279. |
| CX | Miwa, M., et al., "On Development of a Measurement Method of Serum PAF Acetylhydrolase Activity Using an Automatic Analyser, and the Clinical Significance of Serum PAF Acetylhydrolase Defect," <i>Proceedings of Japanese Conference on the Biochemistry of Lipids</i> (1992)34:305-308. |
| CY | Stafforini, D., et al., "Platelet-Activating Factor Acetylhydrolase in Human erythrocytes," <i>Methods in Enzymology</i> (1991)197:411-425 |
| CZ | Kirschbaum, B., "Platelet Activating Factor Acetylhydrolase activity in the urine of patients with renal disease," <i>Clinical Chimica Acta</i> (June 14 1991)199(2):139-146. |
| CAA | Imaizumi, T., et al., "Activity of platelet-activating factor (PAF) acetylhydrolase in plasma from healthy habitual cigarette smokers" <i>Heart and Vessels</i> (1990)5(2):81-86. |
| CAB | Masaharu, M., "Measurement Methods of Platelet Activating Factor (PAF) and PAF Acetylhydrolase (PAFAH) Activity," <i>SRL Hokan</i> (1989)13(3): 36-41. |
| CAC | Schindler, P. W., et al., "Fluorophore-labeled ether lipids: substrates for enzymes of the platelet-activating factor cycle in peritoneal polymorphonuclear leukocytes," <i>Analytical Biochemistry</i> (Nov 1988) 174(2):477-84. |
| CAD | Miyake, M. M., et al., "Characterization of serum platelet-activating factor (PAF) acetylhydrolase. Correlation between deficiency of serum PAF acetylhydrolase and respiratory symptoms in asthmatic children." <i>Journal of Clinical Investigation</i> (Dec. 1988)82(6):1983-1991. |
| CAE | Miwa, M., et al., "Characterization of serum platelet-activating factor (PAF) acetylhydrolase. Correlation between deficiency of serum PAF acetylhydrolase and respiratory symptoms in asthmatic children," <i>Japanese Journal of Inflammation</i> (1988)8(4):327-333. |
| CAF | Satoh, K., et al., "Platelet-activating factor (PAF) acetylhydrolase and plasma lipoproteins: Relative distribution of the activity among lipoprotein classes," <i>Journal of Japan Atherosclerosis Society</i> (1988)16(4):501-504. |

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| | | |
|---|-----|--|
| | CAG | Stafforini, D., et al., "Human Plasma Platelet-Activating Factor Acetylhydrolase. Purification and Properties," <i>Journal of Biological Chemistry</i> (1987)262(9):4223-4230. |
| | CAH | Kawamura, Y., "A Simple Measurement of Plasma Platelet-Activating Factor (PAF) Acetylhydrolase, Normal Level Activity, and Distribution Among Lipoprotein Fractions," <i>Japanese Journal of Clinical Pathology</i> (Oct. 1987)35(10):1149-1153. |
| | CAI | Pritchard, P. H., et al., "The Degradation of Platelet-Activating Factor in the Plasma of a Patient with Familial High Density Lipoprotein Deficiency (Tangier Disease)" <i>Blood</i> (1985) 66(6):1476-1478. |
| | CAJ | Caslake, M. J., et al., "Lipoprotein-associated Phospholipase A ₂ platelet-activating factor acetylhydrolase: a potential new risk factor for coronary artery disease," <i>Atherosclerosis</i> 150(2): 413-9, (June 2000) |
| | CAK | Flegar-Mestric, Z., et al., "Serum platelet-activating factor acetylhydrolase activity in patients with angiographically established cerebrovascular stenosis," <i>Clinical Chemistry and Laboratory Medicine, Processing of the IFFCC-FESCC European Congress 15th Barcelona, Spain</i> : 369-372 (June 1-5, 2003) (Publisher Monduzzi Editore, Bologna, Italy |
| | CAL | Masaki, A., et al., "Determination of Platelet-Activating Factor Acetylhydrolase Activity by Blotting, β -Radioluminescence, and Ultrahigh-Sensitivity Television Camera Detection," <i>Analytical Biochemistry</i> 21(2):295-299 (May 1994). |
| | CAM | Karlan Research Products Corporation, Santa Rosa, CA, "Auto PAF-AH Serum (plasma) platelet-activating factor (PAF) acetylhydrolase assay – Instruction Manual" (2005) |
| | CAN | Cayman Chemical, Ann Arbor, MI "PAF Acetylhydrolase Assay Kit" Catalog No. 760901. |
| | CAO | DiaDexus Inc., "Enzyme Immunoassay for the Quantitative Determination of Lp-PLA ₂ in Human Plasma and Serum" (August 2005). |
| | CAP | Thirkettle, J., et al., "SB-253514 and Analogues: Novel Inhibitors of Lipoprotein-Associated Phospholipase A ₂ Produced by <i>Pseudomonas fluorescens</i> DSM 11579 I. Fermentation of Producing Strain, isolation and Biological Activity," <i>J. Antibiotics</i> (July 2000)53 (7):664-669 |
| | CAQ | Thirkettle, J., et al., "SB-253514 and Analogues: Novel Inhibitors of Lipoprotein-Associated Phospholipase A ₂ Produced by <i>Pseudomonas fluorescens</i> DSM 11579 III Biotransformation Using Naringinase," <i>J. Antibiotics</i> (July 2000)53 (7):733-735 |
| | CAR | Boyd, H. F., et. al., "N-1 Substituted Pyrimidin-4-ones: Novel, Orally Active Inhibitors of Lipoprotein-Associated Phospholipase A ₂ ," <i>Bioorg Med Chem Lett</i> 10 (Dec 2000) 2557-2561 |
| | CAS | Boyd, H. F., et. al., "2-(Alkylthio)pyrimidin-4-ones as Novel, Reversible Inhibitors of Lipoprotein-Associated Phospholipase A ₂ ," <i>Bioorg Med Chem Lett</i> 10 (Feb 2000) 395-398 |
| | CAT | Tew, D. G., et al., "Mechanism of Inhibition of LDL Phospholipase A ₂ by Monocyclic-B-lactams. Burst Kinetics and the Effect of Stereochemistry," <i>Biochem</i> (June 1998) 37:10087-10093 |
| | CAU | Tew, D. G., et al., "Purification, Properties, Sequencing, and Cloning of a Lipoprotein-Associated, Serine-Dependent Phospholipase Involved in the Oxidative Modification of Low-Density Lipoproteins," <i>Arteriosclerosis, Thrombosis Vasc Biol</i> (April 1996) 16(4):591-599. |
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